AT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,155	01/23/2001	Morris Reichlin	OMRF 158 CIP	4427

23579 7590 06/11/2004

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,155	REICHLIN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 8-10,12-15 are under consideration.

2. Regarding applicants comments about the restriction requirement, the restriction requirement enunciated in the previous Office Actions meets the criterion for restriction as elucidated in the MPEP sections 803, 806 and 806.05. Therefore, the restriction is appropriate. The fact that a restriction requirement was not made in a parent case is irrelevant.

3. The rejection of claims 8-10,12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-12 of U.S. Patent No. 6342218 is withdrawn in view of the TD filed 11/8/2003.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 8-10,12-14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in paragraph 7, part 1 of the previous Office Action (*There is no support in the specification as originally filed for the recitation of "prevent the anti-dsDNA antibodies from interfering with protein synthesis" in claim 8. Applicant has indicated that said limitation finds support in Example 2. However, Example 2 does not disclose antiid antibodies. Example 2 discloses anti- dsDNA antibodies that suppress protein synthesis, but includes the additional limitation that said antibodies also cross reactive with Ribosomal Protein S1. There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter*) is withdrawn in view of the amended claims.

6. Claims 8-10,12-14 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action.

There is no support in the specification as originally filed for the recitation of "single chain anti-idiotypic antibody" in claim 8. While the specification discloses "single chain anti-idiotypic Fv fragment", the limitation under consideration encompasses single chain anti-idiotypic antibodies larger than Fv. There is no disclosure in the specification as originally filed of such antibodies. There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

Regarding applicants comments, while the specification discloses "single chain anti-idiotypic Fv fragment", the limitation under consideration encompasses single chain anti-idiotypic antibodies larger than Fv. There is no disclosure in the specification as originally filed of such antibodies. Regarding the various cited passages of the specification to which applicant refers, none of said passages provide support for the scope of the claimed invention which encompasses single chain anti-idiotypic antibodies larger than Fv.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 8,10,12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Weisbart (US Patent 6,232,444).

Weisbart teaches antiid antibodies which bind human antibodies against dsDNA (see column 2, last paragraph, columns 5 and 6, column 3). Weisbart teaches a therapeutic composition containing a F(ab') of said antibody (eg. a single chain antibody) in a pharmaceutical carrier (see column 3, paragraphs one and two). Weisbart teach that the variable light and heavy chains can be joined to exogenous constant regions (eg. a fusion protein, see column 3, fifth paragraph). Weisbart teaches doses of said antibodies for treating disease (see column 3, second paragraph). The mechanisms of action recited in claim 13 and 14 would be inherent in a dosage used to treat the disease because if the anti-dsDNA antibodies were actually causing the disease than the disease would only be treated by preventing production of said antibodies. Weisbart teaches that the antibody can be a recombinant single chain Fv (see column 3, first paragraph and also see column 3, fifth paragraph wherein the VH/VL single subunit is a recombinant single chain Fv).

Regarding applicants comments about human antibodies, claim 9 is the only claim that recites use of a human antiid antibody. Claim 9 is not included in the instant rejection. All of the other claims encompass use of murine antiid antibodies that bind human antiDNA antibodies isolated from SLE patients. Weisbart discloses murine antiid antibody which binds *human antiDNA antibodies isolated from SLE patients* (see columns 5 and 6). Weisbart teaches doses of said antibodies for treating disease (see column 3, second paragraph). The administration of murine antibodies to treat human disease is well known in the art (for example OKT3, a murine antibody approved for human use since the late 1980's). Furthermore, the recitation of an intended use carries no patentable weight in the instant claims and the claimed antibodies could be prepared in a pharmaceutically acceptable carrier (such as tissue culture media) for a variety of other uses (immunoassay, etc). Regarding the antibodies disclosed in Zhang et al., said antibodies are not disclosed in the specification. The specification does not disclose that human antibodies are required for use in the claimed invention. In addition, Weisbart teaches that the antibodies can be chimeric, wherein use of chimeric antibodies in humans is well known in the art. Furthermore, if antibodies with the characteristics found in the Zhang et al. publication are required for use in the claimed invention, the specification would lack enablement for the claimed invention because the antibodies are not disclosed in the specification. Weisbart teaches a therapeutic composition containing a F(ab') of said antibody *(eg. a single chain antibody)* in a pharmaceutical

carrier (see column 3, paragraphs one and two). Weisbart teaches that the antibody can be a recombinant single chain Fv (see column 3, first paragraph and also see *column 3, fifth paragraph wherein the VH/VL single subunit is a recombinant single chain Fv*).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 8-10,12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weisbart in view of Lonberg et al. (US Patent 5,789,650).

Weisbart teaches antiid antibodies which bind antibodies against dsDNA (see column 2, last paragraph, column 5, column 3). Weisbart teaches a therapeutic composition containing a F(ab') of said antibody (eg. a single chain antibody) in a pharmaceutical carrier (see column 3, paragraphs one and two). Weisbart teach that the variable light and heavy chains can be joined to exogenous constant regions (eg. a fusion protein, see column 3, fifth paragraph). Weisbart teaches doses of said antibodies for treating disease (see column 3, second paragraph). The mechanisms of action recited in claim 13 and 14 would occur in a dosage used to treat the disease because if the anti-dsDNA antibodies were actually causing the disease than the disease would only be treated by preventing production of said antibodies. Weisbart

teaches that the antibody can be a recombinant single chain Fv (see column 3, first paragraph and also see column 3, fifth paragraph wherein the VH/VL single subunit is a recombinant single chain Fv). While Weisbart discloses human antiid antibodies of the aforementioned specificity, the particular method disclosed by Weisbart to make said antibodies involves immunizing humans with an antibody that potentially causes disease wherein said immunization could not be practically accomplished for ethical/legal reasons. However, Lonberg et al. discloses that human antibodies of any specificity can be obtained by immunizing transgenic mice wherein said mice have been made transgenic with the appropriate genes that allow said mice to produce human antibodies (see column 3, last paragraph). Lonberg et al. disclose that said methods can be used to produce human antibodies wherein a human could not be ethically immunized with an antigen (for example, see column 8, penultimate paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because while Weisbart discloses human antiid antibodies of the claimed specificity, the particular method disclosed by Weisbart to make said antibodies involves immunizing humans with an antibody that potentially causes disease wherein said immunization could not be practically accomplished for ethical/legal reasons and Lonberg et al. discloses that human antibodies of any specificity can be obtained by immunizing transgenic mice wherein said mice have been made transgenic with the appropriate genes that allow said mice to produce human antibodies. One of ordinary skill in the art would have been motivated to do the aforementioned because Weisbart discloses human antiid antibodies of the aforementioned specificity and the potential uses of such antibodies and Lonberg et al. disclose that said methods can be used to produce human antibodies wherein a human could not be ethically immunized with an antigen.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-2720841. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1644

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644